

A closer look at 'information' to patients: Making the right choice for Europe

Brussels, 2 December 2009



Overview

On 2 December 2009, an expert meeting at the European Parliament on the legislative proposals for 'information' to patients was hosted and chaired by MEP Thomas Ulmer from the European People's Party and MEP Carl Schlyter from the European Greens. The meeting brought together 93 participants representing a variety of stakeholder groups, including Members of the European Parliament; mainstream and medical press; patient groups, consumer organisations, health insurers, and pharmaceutical industry representatives from industry associations and individual pharmaceutical companies.

The aim of the meeting was to raise awareness about the real information needs of EU citizens with regard to prescription medicines, and to highlight potential problems with the European Commission's 'information to patients' proposal in meeting those needs.

The meeting began with an introduction from MEP Thomas Ulmer, followed by a panel of speakers to present the case for relevant, reliable, comparative health information that is adapted to users and available from independent sources.

Summary of speakers' presentations

Barbara Mintzes, Assistant Professor at University of British Columbia (Canada), provided a historical overview of the 'medicines' information' debate and presented recent examples of "information" provided by the pharmaceutical industry to the public in Europe.

Ilaria Passarani, Head of Health Department at European Consumers' Organisation (BEUC), conveyed BEUC's views on the legislative proposal from the broader perspective of European consumers.

Jörg Schaaber, President of the International Society of Drug Bulletins (ISDB), presented examples of information provided by the industry to medical professionals and the public and talked about his experience as a provider of independent information.

Cédric Diat, from the Association François Aupetit (AFA), talked about the needs and demands of patients with regard to information about prescription medicines, from the perspective of a grassroots patient organisation.

Anne Sophie Parent, AGE - European Older People's Platform, spoke on behalf of EU citizens over the age of 50, who are the main consumers of medicines, as they often live with several conditions and use numerous medicines at the same time.

The powerpoint presentations from the speakers are available to download here:

<http://www.aim-mutual.org/index.php?language=en&page=17&id=200>

EVENT MEMO

Overtoom 60, II
1054 HK Amsterdam
The Netherlands
terri@haiweb.org
www.haiweb.org



The discussion session brought out a number of comments and concerns about the legislation itself; the policy discussion around the proposals; and the stakeholders involved in the debate surrounding information on prescription medicines in the European Union.

The main issues arising from the plenary discussion were as follows:

What information do patients and consumers want?

One of the weaknesses of the proposed legislation is that it does not arise from any assessment to determine what information patients and consumers need, and how and from whom they wish to receive it. Without this knowledge as a sound basis for the EU Commission's proposals, the legislation lacks legitimacy. Patients and consumers should be able to make treatment decisions based on unbiased, accurate, and comparative information. Prescription medicines are used to treat conditions that require the expertise and supervision of qualified healthcare professionals and information about these products should not be treated lightly.

Bernardette Vergnaud MEP, Vice-president of the Committee on Internal Market and Consumer Protection and Shadow Rapporteur on pharmacovigilance, made the point that,

"Health is not a market like any other, patients are not mere consumers they are citizens; health certainly has costs but cannot have a price."

Anne-Sophie Parent, representing the European Older People's Platform agreed, saying that,

"What we hear from our membership is that what they want is really something they can trust, that has been tested, so that they can be aware of the adverse reactions that could come up."

What information pharmaceutical companies can provide

The pharmaceutical industry already plays a role in providing information through the product leaflet that accompanies prescription medicines, which is evaluated by drug regulatory agencies. Beyond this, current legislation allows pharmaceutical companies to answer to written requests from patients, a function that was highlighted by Ilaria Passarani, from BEUC, in response to one patient group, who described difficulties in requesting information held by the industry on research into rare diseases and conditions.

On the issue of current regulations on industry provision of information, Anne-Sophie Parent, from AGE commented,

"I am surprised that...a patient organisation...does not already have access to all the research which is going on. This information is not available to the public at large, but is available for those that are following the dossier and later to the EMEA [European Medicines Agency]. Why then would the industry need to provide you with this information? That for me is not very clear."

Push vs. pull information

The question of "push vs. pull" information was also raised by several participants. Whilst improving the provision of information related to direct written requests by patients about their prescription medicines ("pulled" information) deserves policy consideration, information provided or "pushed" by companies treads the fine line between 'information' and 'advertising'. According to Barbara Mintzes, the text of the draft legislation allows for information to be communicated in media, including the internet and undefined health publications, and it does not preclude unbranded information on billboards; communications that do not qualify as 'pulled' information solicited by the patient or consumer.

The ISDB representative expanded the point about “push vs pull” information, arguing that there could even be a “push to pull”, where unbranded ‘disease awareness’ announcements direct people to websites or publications encouraging them to ‘pull’ for information about one particular branded product or treatment, without including all the relevant, unbiased and comparable information about treatments for the disease, including the option not to treat.

As was noted in the previous section, current legislation already allows for companies to answer direct written requests from patients.

Can the pharmaceutical industry provide ‘unbiased information’ about their products?

In discussing the issue of the role of industry as information provider, two MEPs made interventions casting doubt on the ability of pharmaceutical companies to provide relevant, reliable, and comparative health information adapted to users.

MEP Gilles Pargneux addressed the issue of conflicts of interest and in discussing the role of pharmaceutical companies as information providers, he said,

“I’m not against the pharma industry because I think they do a grand job in innovation and research. The pharmaceutical industry is supposed to turn out drugs, but too often the information provided is for commercial rather than purely informational purposes.”

MEP Bernardette Vergnaud also stated the importance of ensuring independence between the pharmaceutical industry and information providers,

“because one cannot be judge and party...independence is fundamental not only for patient safety, but also for the perception of European citizens towards pharmaceutical companies.”

The role of the media industry as the chief advocate for this proposed directive was also discussed. However, panellist Jörg Schaaber characterised the relationship between the pharmaceutical and media industries on this issue as “a happy marriage” from which both would benefit from increased sales and advertising revenue, respectively.

Where more information is needed

There is no doubt that there are gaps in information available to the public on prescription medicines. Medicines’ information researcher, Barbara Mintzes, highlighted two areas where information was clearly lacking: full publication of all clinical trials data and access to the complete PSUR (Periodic Safety Update Report).

However, when one patient group representative called for access to un-validated information and information on prescription medicines for unapproved (off-label) uses held by the industry, there was opposition from the panel. Barbara Mintzes, Jörg Schaaber (ISDB) and Anne-Sophie Parent (AGE) rejected the idea that information that had not been validated was appropriate for communication to the public. Barbara Mintzes described the idea of public dissemination of this unvalidated type of information as “very concerning and should not be permitted”.

Jörg Schaaber from ISDB, whose presentation gave examples of selective publication of clinical trials data, was also sceptical about the likelihood of companies providing all studies related to a product regardless of the outcomes, noting that any expectation of unbiased or complete information directly from the company was “a bit naïve”.

Other stakeholders also weighed in, setting out what an ‘information on prescription medicines’ policy should look like in the EU. In his intervention, MEP Gilles Pargneux, said that he did not see a “medical reason why the pharmaceutical industry should provide information directly to the patient” and instead called for “a structure where we can monitor what sort of information is available so we can tell patients what is correct and necessary.”

Who represents patients and consumers in this debate?

There was an apparent division in the opinions voiced by some patient groups and consumer groups at the meeting, with some organisations more in favour of the proposals whilst others felt that the draft legislation was inappropriate for the needs of the patients and consumers they represent.

Cédric Diat, from (AFA), whose presentation described the information needs of patients at grassroots level, responded:

“We are connected directly into the group. We have information centres and calls every day with patients. What I gave you in my presentation was really something we see every day on the ground.”

Axel Singhofen, the Health and Environment Policy advisor for the European Greens commented:

“I perceive different positions from patient organisations. Cédric was critical of proposal but the views of Eurordis and the European Patients’ Forum are more positive. Who is now representing whom?”

In response, the AFA representative was uncertain, saying, “I can notice the differences. We are more critical. Why are we more critical? I cannot say.”

Ilaria Passarani, Head of Health Department at BEUC also urged policymakers to consider that the legislation would apply to all EU citizens, and not only to specific groups of patients and citizens.

These differences highlight the importance of a consultation process with input from a variety of patient groups and consumer organisations in order to ensure that the full spectrum of views from EU consumers and patients are taken into account. The example of AGE demonstrates that an organisation can represent a significant bloc of prescription medicines’ consumers, who may not be otherwise represented by a specific patient group, but whose views are nonetheless, vital to the debate.

What next for the proposal

The European Patients’ Forum perspective on the proposed legislation was to review it as, “to throw it away would be a grave mistake”. EPF spoke of the importance of the quality criteria developed by the pharmaceutical forum but considered the panellists perspectives to be “one-sided” in their critiques of the proposals.

During the discussion session, panellist Ilaria Passarani from BEUC invited representatives from the pharmaceutical industry present at the meeting to share their views and opinions. However, none of the invited participants from pharmaceutical industry associations or individual pharmaceutical companies chose to make an intervention.

In a final contribution from the floor, Jim Murray, former Director of BEUC, described the attempt to draw a distinction between ‘information’ and ‘advertising’ as “nonsense”. Mr Murray went on to outline the dangerous consequences of conflating ‘information’ and ‘advertising’.

“1. In advertising, the information is given for the purposes of promoting a product; 2. If we can make that distinction for the pharmaceutical industry, then the food industry will want to do the same. I.e. McDonald’s could give information about their products without being subject to advertising laws; 3. By saying that the so-called information is not advertising, it can be taken outside the remit of advertising laws and could mean that it is opened up to unfair commercial advertising practices.”

Final comments from the Chair, Carl Schlyter MEP

MEP Schlyter thanked the speakers and participants for their contributions and ended the meeting by concluding that the Commission’s proposal seemed to be almost universally unpopular. He also commented that he did not perceive any call for direct information about prescription medicines from manufacturers by the public. He viewed the ‘information’ responsibilities of the pharmaceutical industry as a role that should be confined to answering consumers’ questions, and designated regulatory agencies as the bodies who should take responsibility for delivering unbiased information to EU citizens. Whilst recognising the importance of granting consumer access to neutral information about medicines, he believed that the current proposal risked giving the pharmaceutical industry a carte blanche and facilitating disguised advertising.